

Inositol SAP

Science-based myo-Inositol powder for the management of polycystic ovary syndrome*

Polycystic ovary syndrome (PCOS) is the most common cause of ovulatory disorders and female infertility.* Signs and symptoms of PCOS may include anovulation or menstrual irregularities; ovarian cysts on ultrasound; hyperandrogenism including hirsutism, acne, and alopecia; insulin resistance; and obesity.* Insulin resistance and secondary hyperinsulinemia appear to play a causative role in the development of PCOS.* In addition, PCOS patients suffer from elevated oxidative stress and systemic inflammation.* *myo*-Inositol has been suggested as a first-line therapy in the management of PCOS, and has been shown to be effective in mitigating the symptoms of this syndrome and its associated comorbidities.*

SUPPLEMENT FACTS

Serving Size: 1 Scoop	Amount Per Serving	Servings: 125	% Daily Value
Inositol (<i>myo</i> -inositol)	4 g		**

‡ Percent Daily Values are based on a 2,000-calorie diet.

**Daily Value not established

This product is non-GMO.

Contains no: Gluten, soy, wheat, eggs, dairy, yeast, citrus, preservatives, artificial flavor or color, added sweeteners, allergens, or starch.

DIRECTIONS FOR USE

Adults: Mix 1 scoop to 8 oz. (250 ml) of water or juice one to three times daily or as directed by your healthcare practitioner. Consult a healthcare practitioner for use beyond 6 weeks.

INDICATIONS

Inositol SAP Helpful in restore ovulation, oocyte quality, and fertility, as well as to normalize menstrual irregularities,* and can be used to:

- Restore normal ovarian function in women with oligomenorrhea and polycystic ovaries.*
- Improve oxidative stress associated with PCOS.*
- Support management of PCOS's hormonal and metabolic conditions by promoting healthy glucose metabolism.*
- Improve acne, hirsutism, and hyperandrogenemia associated with PCOS.*

SAFETY

myo-Inositol is generally well tolerated. At therapeutic doses up to 4 g/d, no significant adverse events have been reported for the oral supplementation of *myo*-inositol in studies for up to 6 months.

CAUTIONS AND WARNINGS

For adult use only. Consult a healthcare practitioner if you are pregnant or breast-feeding. Discontinue use and consult a healthcare practitioner if you experience nausea, tiredness, headache, dizziness, abdominal pain, flatulence or soft stools.

PURITY, CLEANLINESS, AND STABILITY

All ingredients listed for all **Inositol SAP** lot numbers have been tested by an ISO 17025-accredited third-party laboratory for identity, potency, and purity.

*** These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**

Scientific Advisory Panel (SAP):
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POLYCYSTIC OVARY SYNDROME (PCOS)

Polycystic ovary syndrome (PCOS) is the most common cause of ovulatory disorders and female infertility. It is estimated that this syndrome affects 6–10% of women of childbearing age. Increased insulin levels and impaired glucose tolerance may play causative roles in the development of hyperandrogenemia, the metabolic and reproductive changes in PCOS, through their synergism with luteinizing hormone (LH) to enhance androgen production.^[1, 2, 3, 4, 5, 6]

Comorbidities, signs and symptoms of PCOS commonly include features of metabolic syndrome — including insulin resistance, obesity, and dyslipidemia —, in addition to hyperandrogenemia, reflected in hirsutism, alopecia, and acne. Insulin resistance appears in both obese and nonobese women diagnosed with PCOS.^[3, 7]

Since the association of hyperinsulinemia, impaired glucose tolerance and insulin sensitivity with PCOS was realized, conventional treatments of this disorder have included pharmaceutical insulin-sensitizing drugs such as metformin, oral contraceptives for the regulation of menstruation, antiandrogenic agents such as spironolactone to address hirsutism, and clomiphene to induce ovulation if desired.

Inositol-containing phosphoglycans (IPGs) have been discovered to play a role in activating enzymes that control glucose metabolism.^[1, 2, 7] It is speculated that a decrease in the availability or utilization of IPG mediators may contribute to insulin resistance in the pathogenesis of PCOS. Up to 50–70% of women diagnosed with PCOS demonstrate insulin resistance and impaired glucose tolerance.^[2, 3, 8]

METABOLIC, LIPID, AND HORMONAL EFFECTS OF MYO-INOSITOL

myo-Inositol has been shown in multiple prospective studies to significantly reduce plasma LH, testosterone, free testosterone, HOMA index, and insulin levels within 3 months.^[4, 9] Constantino et al. performed a randomized, double-blind, placebo-controlled trial using myo-inositol and found that myo-inositol supplementation at 4 g/d significantly reduced blood pressure, cholesterol, triglyceride, testosterone, and SHBG levels.^[5] Minozzi et al. compared the effects of 4 g/d myo-inositol in combination with oral contraceptives versus oral contraceptives alone and found that combination therapy may be more effective than oral contraceptives alone at modulating pertinent hormone levels in PCOS.^[10]

HIRSUTISM, ACNE, AND SKIN DISORDERS

myo-Inositol has been shown to reduce symptoms of hirsutism and acne associated with PCOS after 3 months. The decrease in the number of cases exhibiting hirsutism of all severities in this study was statistically significant at 3-month and 6-month follow-ups. 30 % of cases exhibited complete remission of hirsutism symptoms by the 6-month follow-up. The number of cases exhibiting acne also significantly decreased over the 6-month trial, with complete disappearance being reported in 53% of cases.^[6]

FERTILITY

In a study by Genazzani et al., 2 g/d myo-inositol supplementation over 6 months restored menstrual cyclicity in all amenorrheic and oligomenorrheic subjects.^[9] 88% of amenorrheic subjects supplemented with 4 g/d myo-inositol in a study by Papaleo et al. achieved at least one spontaneous menstrual cycle within 6 months. 40% of subjects in the same study achieved clinical pregnancy, with no incidence of multiple pregnancy.^[6] Raffone et al. compared the efficacy of 4 g/d myo-inositol and metformin in combination and alone and concluded that myo-inositol alone is more effective than metformin alone as first-line treatments for the restoration of normal menstrual cycles and in the treatment of infertility.^[2] Furthermore, Morgante et al. establish that metformin alone, or in combination with clomiphene, has no advantage in inducing ovulation in patients with PCOS, and should be reserved for patients exhibiting glucose intolerance.^[7] It is believed that myo-inositol may improve oocyte quality and ovarian function via modification of calcium signaling, required especially in the final stages of oocyte maturation.^[2, 11, 12]

OXIDATIVE STRESS IN PCOS

PCOS patients usually present with an elevated production of reactive oxygen species and systemic inflammatory status.^[13] Specifically, such inflammatory status has been reported to induce erythrocyte membrane alterations.^[13] myo-Inositol administration can be effective in reducing oxidative stress associated with PCOS, in addition to improving insulin resistance and metabolic parameters. PCOS patients who received myo-inositol supplementation at 1200 mg/day for 12 weeks significantly improved the oxidative status of red blood cells compared to their counterparts in the placebo group.^[13]

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